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Peter F Corless  
Dike Bronstein Robert & Cushman Edwards & Angell  
Intellectual Property Pratice Group  
130 Water Street  
Boston, MA 02109

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/674,337

Applicant(s)  
Mori et al.

Examiner  
Christian L. Fronda

Art Unit  
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 and 1 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of Group I, claims 1-7, and SEQ ID NO: 1 in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 8-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As previously stated in the Office Action dated 10/03/2002 ( paper No. 15), the requirement to select a single amino acid sequence of SEQ ID NOS: 1, 3, 5, 7, 9, 11, 13, 15, 17, 21, or 23 is not to be construed as a requirement for an election of species since each of the amino acid sequences recited in alternative form is not a member of a single structurally and functionally related genus. Each of the recited amino acid sequences constitutes an independent and patentably distinct invention, and separate searches are required for each of the amino acid sequences.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-7 and SEQ ID NO:1 are under consideration in this Office Action.

### ***Claim Objections***

3. Claims 3, 5, and 7 are objected to because of the following informalities: Claims 3, 5, and 7 are objected to because they recite non-elected subject matter, specifically, SEQ ID NOS: 3, 5, 7, 9, 11, 13, 15, 17, and 21. Applicant is required to cancel the claim(s), or amend the claim(s) to recite the elected subject matter of SEQ ID NO: 1.

### ***Claim Rejections - 35 U.S.C. § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-7 are rejected under 35 U.S.C. 101 because the claims are directed toward non-statutory subject matter.

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6. Claims 1-7, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the specific "amino acid sequence having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids" is not known and not defined in the specification.

Claim 2 is vague and indefinite because the meaning of the phrase "orginiated from barley" is not known and not defined in the specification.

Claim 3 is vague and indefinite because the meaning of the phrase "comprising having" is not known and not defined in the specification.

Claim 4 is vague and indefinite because the meaning of the phrase "orginiated from Arabidopsis" is not known and not defined in the specification.

Claim 5 is vague and indefinite because the meaning of the phrase "comprising having" is not known and not defined in the specification.

Claim 6 is vague and indefinite because the meaning of the phrase "orginiated from Oryza sativa" is not known and not defined in the specification.

Claim 7 is vague and indefinite because the meaning of the phrase "comprising having" is not known and not defined in the specification.

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***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention encompass any nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 "having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids". The specification, however, only provides the following representative species encompassed by the invention: an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1. The specification also fails to provide a written description of the specific amino acid residues that must be deleted, substituted, or added to SEQ ID NO: 1 and the specific amino acid residues that must not be altered in order to preserve nicotianamine synthase activity. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claims 2, 4, and 6 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

11. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1; does not reasonably provide enablement for any nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 "having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids".

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass for any nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 "having deletion in a part thereof, being

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substituted by the other amino acids or being added with other amino acids”.

The specification provides guidance and examples for making an isolated an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1. However, the specification does not teach the specific catalytic amino acids and the structural motifs which are essential for enzyme structure and activity/function and cannot be altered. The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that “...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation” (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that “...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins” (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed nicotianamine synthase is enormous and entails selecting specific amino acid residues to change (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 to make the claimed nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1 “having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids” and determining by enzymatic assays whether the protein has nicotianamine synthase activity. The specification does not provide guidance with respect to the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Thus, searching for the specific amino acid residues to change (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting protein has nicotianamine synthase activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 2, 4, and 6 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

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***Claim Rejections - 35 U.S.C. § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Higuchi et al. (Plant Soil, 165: 173-179 (1994), Reference 'AB' cited on the Information Disclosure Statement, form PTO-1449, dated 8/28/01, Paper No. 14).

The claims encompass any nicotianamine synthase of any amino acid sequence since the claim recites that the claimed nicotianamine synthase comprises an amino acid sequence of SEQ ID NO: 1 "having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids". Further, no patentable weight is given to the species of plant that the claimed nicotianamine synthase is obtained from.

Higuchi et al. teach an isolated and purified nicotianamine synthase from barley roots (see entire publication). In absence of facts to the contrary, the nicotianamine synthase taught by Higuchi et al. inherently comprises an amino acid sequence of SEQ ID NO: 1 "having deletion in a part thereof, being substituted by the other amino acids or being added with other amino acids" since the claims encompass any nicotianamine synthase of any amino acid sequence. Thus, the reference teachings anticipate the claimed invention.


***Conclusion***

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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PONNATHAPURA ACHUTAMURTHY  
SUPERVISOR, EXAMINER GROUP 1600  
TEL: (703) 308-3804